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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,462	11/24/2003	Thomas J. Boyd	7052-01	4081

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,462	BOYD ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mannara (US 4,003,971) in view of Thombre et al. (US 20020034542).

Mannara teaches particles or speckles useful for the incorporation into clear dentifrices such as dental paste, gels and creams, as recited in claim 6. The incorporation of the speckles into the dentifrice provides an attractive appearance. In general dentifrices having uniformly distributed speckles in accordance with the

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invention contain about 0.1 to 50% by weight of speckles, preferably from 0.5 to 20%, and most preferably about 0.5 to 10% (col. 4, lines 18-25), as recited in claim 7. The speckles include, in addition to organic binders, one or several functional and/or aesthetic dentifrice components preferably one selected from the group consisting of anticaries agents (fluoride salts), antimicrobial agents, colorants, surface active agents, enzymes, astringents, flavors, sweeteners, optical brightening agents and polishing agents (col. 11, lines 50-56), as recited in claims 2, 4, 5 and 7-11. The concentration of functional and/or aesthetic component is about 0.01 to 25% of the speckle. In an especially preferred embodiment of the invention the speckling material contains 0.01 to 10% by weight of a conventional dentifrice colorant, in addition to any other functional and/or aesthetic dentifrice components (col. 3, lines 29-34). The binding agent employed in preparing the speckles according to the invention is any of a large number of physiologically acceptable organic compounds which are known to be compatible with functional and/or aesthetic dentifrice components so as to form a stable speckle or agglomerate therewith (col. 4, lines 35-41). These binders include water-soluble polymers and gels such as cellulose (col. 4, lines 35-46) as in claim 1. Generally, a flavoring agent is present in a concentration of about 0.1 to 10% of the dentifrice (col. 8, lines 10-12). When the flavoring is incorporated into the speckle, the percentage would correspond to that of claim 12. The dentifrice itself contains gelling agents such as alkali metal carboxymethyl cellulose, hydroxymethyl carboxyethyl cellulose, and starch. The reference differs from the instant claims insofar as to not teach the speckles contain a starch.

Thombre et al. teaches rapidly disintegrating and fast-dissolving solid dosage forms that comprise of a pharmaceutically acceptable polymer (see abstract). Pharmaceutically acceptable polymers disclosed herein include all manmade and natural polymers and polymeric materials that are compatible with the processes. hydroxypropyl methylcellulose (HPMC) or mixtures of polymeric materials with each other or with other carrier materials such as polyvinyl alcohol, polyvinylpyrrolidone or acacia. A preferred polymeric material of the invention is high amylose starch (paragraph 0019). The medication can be added directly to the polymeric material prior to extrusion, additives such as coloring agents, flavoring agents and preservatives can be added as well (paragraph 0042). The dosage forms in the reference can also be formed into different shapes and designs (paragraph 0033), as recited in claim 3 and 13. The reference differs from the instant claims insofar as to not use the polymeric mixtures in a dentifrice.

It would have been obvious to one of ordinary skill in the art to have used the polymers in the secondary reference to make the speckles in the primary reference motivated by the desire to be able to deliver therapeutic agents incorporated into the speckles rapidly upon brushing, to ensure the speckles dissolve when in the mouth, to be able to shape the speckles to the desired shape or thinness and to use materials commonly found in toothpaste.

2) Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mannara in view of Graff-Andersen et al. (US 5,869,029).

The primary reference is as stated above including how the reference differs from the instant claims.

Graff-Andersen et al. discloses that two types of toothpaste are widely produced; cream or opaque; and transparent or translucent. Certain compounds used in toothpaste as thickeners and binders form lumps in the compositions. This prolongs the manufacturing process because of the desire to remove the lumps to create a uniform composition. The most commonly used thickeners or binders include hydroxyethyl cellulose (col. 1, lines 23-41). Other widely used thickeners and binders are water-soluble or water swellable polymers. The reference teaches the treatment of these compounds with polyol to stop the formation of lumps when added to dentifrice compositions. The preferred polymers for the disclosed invention are polysaccharides which include cellulose ethers, guar, starch and chitin to name a few. These polysaccharides may also be used in mixtures (col. 2 lines 36-67 and col. 3, lines 1-32). The reference differs from the instant claims insofar as to not disclose using the binders as flakes that contain functional and/or aesthetic components in a clear dentifrice.

It would have been obvious to one of ordinary skill in the art to have used polysaccharides such cellulose ethers and starch of the secondary reference and incorporated them into the clear dentifrice of the primary reference motivated by the desire to use materials commonly found in toothpaste that can form agglomerates such as flakes that are stable in the presence of other components found within the toothpaste compositions.

Obvious-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,669,929.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a dentifrice that contains film flake matrix of that are decorative and aesthetically shaped. The dentifrice in both cases is a clear gel. The flakes make up the same weight percents of the dentifrice; have a colorant and flavorant, which has the same weight composition. The flake film matrix is made up of the same material (water soluble hydroxyalkyl cellulose polymer and as starch) and they

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may contain a therapeutic agent, a cosmetic constituent, an antibacterial agent or a calcium or fluoride salt. The only differences between the two sets of claims are the patented claims are more specific than the instant claims and the instant claims make reference to the film flake matrix being a two-dimensional flake which is obvious the patented film flake matrix are because of the term "film".

Claims 1-13 are rejected.

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Lezah Roberts', followed by a long horizontal flourish line.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', written in a cursive style.